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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,911	12/27/2001	Margarete Focke	0273-0005	6842

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/026,911	Applicant(s) FOCKE ET AL	
	Examiner Patrick J. Nolan	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004 and 15 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-24 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) 14-24 and 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6-20-02</u> | 6) <input type="checkbox"/> Other: _____  |

PD

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1. Claims 1-9, 14-24 and 28-33 are pending.
2. Applicant's election with traverse of Group I, claims 1-9 in the reply filed on August 9<sup>th</sup> 2004 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to search all the groups together.

To clarify the record, in the restriction in the section where distinctness is demonstrated, the second full paragraph should have been distinguishing Group I from Group III. To answer Applicant's arguments methods of making and using a product are clearly distinct inventions from the product as one could use the product for a distinct use or make the product by another method, as disclosed in the original restriction.

The requirement is still deemed proper and is therefore made FINAL.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of the base claim is drawn to any peptide fragment of any allergen that has 3 successive solvent exposed amino acids. This claim could easily read upon thousands of known allergen peptides. The only protein whose amino acid solvent regions have been fully described in the specification is Bet v1. The description of one genus protein and the peptides therein, does not adequately describe the thousand of additional proteins and peptides encompassed by the claimed invention. As such, the specification lacks written description for the claimed invention.

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Friedl-Hajek as evidenced by Gajhede et al (reference AD1 on the IDS submitted 6-20-02).

Friedl-Hajek et al., discloses peptides that are derived from Bet v 1, wherein said peptides are 12-22 amino acids in length and in pharmaceutical compositions (see page 480, in particular). Gajhede et al., discloses the solvent exposed residues in Bet v1, and at least peptide 31-51 as disclosed in Friedl-Hajek, meets the limitation of three consecutive solvent exposed amino acids.

The prior art teachings anticipate the claimed invention.

7. Claims 1-5, 7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by US patent 6,878,376.

The '376 patent teaches peptide fragments of the allergen protein, that are within the range 8-50 amino acids in length, can be truncation mutants, in pharmaceutical compositions, with adjuvant, and wherein one mutant peptide can be made by a discrete point mutation or one or more amino acid substitutions (see columns 4-8 and 13 in particular). While the patent does not specifically state solvent exposed residues in its peptides it does discloses selecting peptides with amino acids that are hydrophilic and are likely to interact with antibodies (i.e. solvent exposed).

The prior art teachings anticipate the claimed invention.

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8. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

May 31, 2005